



Stop Animal Exploitation NOW!

Dr. Danny Jacobs, President,
Oregon Health & Science University
3181 S.W. Sam Jackson Park Rd.
Portland, Oregon 97239-3098
via email: president@ohsu.edu

11/16/19

President Jacobs,

I am writing to you today to insist that you take administrative action to permanently terminate a scientific project which has been reported as violating both the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Animal Welfare Act. The incidents connected to these projects have led to the levying of three separate citations against Oregon Health and Science University in one USDA inspection, two of which were of the much more serious DIRECT nature. Also, it is highly likely that these projects have also been the cause of previous USDA citations and additional compliance issues. The incidents which led to these reports and citations also led the OHSU IACUC to suspend this project. While this suspension was a good first step, it was nowhere near sufficient to resolve this 'scientific' bungling. These projects must be permanently terminated.

The OHSU report of the incidents connected to these suspended experiments lists a multitude of problems:

" . . . conduct of surgery using poor sterile technique; use of materials and methods for euthanasia that were not on the approved protocol; failure to document training of laboratory staff; failure to assure staff compliance with the occupational health requirements; use of containers that could not be adequately sterilized to store surgical dressing supplies; failure to notify veterinary staff of animal health issues as required in the approved protocol; and failure to maintain required veterinary medical records. The CWC IACUC determined that these events collectively indicated inadequate oversight of the animal care and use program by the PI in the PI's laboratory and noncompliance with PHS Policy and the Animal Welfare Act and Regulations."

The form generated by the NIH's Office of Laboratory Animal Welfare from OHSU's initial telephone report of the incidents adds more crucial information:

"2 protocols under one PI suspended. Animals transferred to holding protocol, Recurring issues. . . death of ferret due to surgical issues requiring euthanasia under anesthesia. Euthanasia method not per protocol. . . Also, OHS (Occ. Health) issues re: marmoset exposure. Animal health record issues. USDA also noted head caps not properly maintained. (early June)."

A USDA inspection report dated 6/3/19 also addresses these incidents:

"A lab group was found on April 2, 2019 to be conducting a surgery with poor sterile technique. Department of Comparative Medicine (DCM) veterinarians and technicians in attendance stepped in to ensure the welfare of the ferret. This pilot surgery ran into unexpected anatomical complications, and the animal was euthanized under anesthesia. The materials and methods for this euthanasia were not on the approved protocol."

The USDA inspection then goes on to discuss many of the same issues and the OHSU report filed with OLAW, improper storage of supplies, improper veterinary records, etc.

This inspection issued two of the more serious DIRECT citations for inadequate veterinary care, as well as a citation relevant to personnel qualifications.

It is very disturbing that the staff connected to these projects was found to be unqualified, and that the veterinary staff had to step in, considering that according to the National Institutes of Health website this project was first funded in 2016, approximately four years ago. It is equally disturbing that this project still has two years of funding remaining. I shudder to think what could happen in the two remaining years.

It is apparent from other documents that these are likely not the first serious compliance issues relevant to the projects connected to this principal investigator.

These projects discuss the use of ferrets, and marmosets. You will note from the 6/3/19 USDA inspection report (attached -- which clearly discusses the same incidents as the OHSU report to OLAW), these issues evidently occurred at OHSU's site 1. The animal inventory attached to the inspection report lists only three ferrets, and 4 marmosets. This is very likely only enough animals for one project involving each species.

An earlier (7/19/18) USDA inspection, also of site 1, lists a small number of ferrets (5) and marmosets (4). Therefore, it is highly likely that any issues listed in this report, namely depriving both ferrets and marmosets of water, are connected to exactly the same projects.

Additionally, an OHSU internal record lists further compliance problems which involved ferrets that discusses the issues like this:

"This lab studies normal auditory function. Ferret's head needs to be fixed in place for craniotomy & electrode placement. This requires head-post using acrylic & screws to attach to skull. . . . Three ferrets lost head caps in June."

It is quite apparent from all of these records that these highly invasive projects have had ongoing problems for at least two years. One ferret has died in a botched surgical procedure. Ferrets and marmosets were improperly denied water. Veterinary staff had to intervene in a surgical procedure. Surgeries were not performed aseptically. Animals were denied veterinary care. Veterinary records were not maintained, etc.

It might be easier to list the few things that these pseudo-scientists did correctly.

It is obvious that serious non-compliance issues have existed in these projects for multiple years, impacting multiple animals. These issues would clearly also make any information generated by these projects scientifically meaningless. A significant number of animal lives have been taken uselessly, and hundreds of thousands in taxpayer dollars have been wasted.

This must stop, and it must stop now.

OHSU's reputation, and the lives of a significant number of animals are both at stake. The only way that you can prevent further damage to OHSU's reputation as well as suffering to many animals, is to permanently terminate these projects, and return all federal funding from this project to the National Institutes of Health. To do anything else would make the OHSU administration complicit in the fraudulent use of federal funding in scientifically useless experiments which needlessly kill animals.

Therefore, I am calling upon you, and the OHSU IACUC, to permanently terminate these projects: IP211 and IP1561, as well as the animal use privileges for all staff connected to these botched experiments. The lab staff connected to these ill-fated experiments have bungled these projects so seriously that no useful information can come from them, and the results should not be published because too many uncontrolled variables have been introduced into the protocols, and in light of the fact that medical journals typically require full compliance with all federal regulations, the compliance failures connected to these projects should also prohibit their publication.

I will await action from your office, and expect to receive a reply within five (5) business days.

Sincerely,

A handwritten signature in black ink that reads "Michael A. Budkie, A.H.T." with a stylized flourish at the end.

Michael A. Budkie, A.H.T.,
Executive Director, SAEN

Attachments: 2 Oregon Health & Science University USDA inspections, OHSU Correspondence, and reports



**Research & Innovation
Office**

tel 503 494-1083
fax 503 494-1099

Dana Director, PhD
Vice President of Research
Administration & Senior
Staff Officer

director@ohsu.edu
www.ohsu.edu/research

Mail code: L335
3181 S.W. Sam Jackson
Park Rd.
Portland, OR 97239-
3098

September 10, 2019

Dr. Brent Morse
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

The Oregon Health & Science University (OHSU), in accordance with Assurance D16-00195 (A3304-01) and PHS Policy IV.F.3., provides this final report regarding the suspension of animal activities of two protocols by the Central and Waterfront Campus (CWC) Institutional Animal Care and Use Committee (IACUC). A unanimous vote of the quorum present at the June 12, 2019 meeting of the OHSU CWC IACUC suspended animal activities covered by two animal use protocols (IP211; IP1561) held by a single investigator. The research investigates neurophysiological processing of sound in awake behaving marmosets (IP211) and auditory brain function and plasticity in ferrets, gerbils and mice (IP1561). The suspension was reported initially to OLAW by the Director, Animal Care & Use Program on June 13, 2019.

The suspensions were in response to non-compliant items related to protocol IP1561. There were no non-compliant items associated with protocol IP211, however the IACUC suspended both protocols comprising all animal work under the direction of the Principal Investigator (PI).

Specific non-compliant items included conduct of a surgery using poor sterile technique; use of materials and methods for euthanasia that were not on the approved protocol; failure to document training of laboratory staff; failure to assure staff compliance with occupational health requirements; use of containers that could not be adequately sterilized to store surgical dressing supplies; failure to notify veterinary staff of animal health issues as required in the approved protocol; and failure to maintain required veterinary medical records. The CWC IACUC determined these events collectively indicated inadequate oversight of the animal care and use program by the PI in the PI's laboratory and noncompliance with PHS Policy and the Animal Welfare Act and Regulations.

Upon suspension, the Department of Comparative Medicine (DCM), directed by the Attending Veterinarian for the CWC, assumed responsibilities for care of the ferrets, gerbils and mice immediately. Daily husbandry for the marmosets was assigned to an experienced laboratory member following consultation with the Attending Veterinarian and careful consideration for the

best interests of the animals. All other laboratory personnel were denied access to the animal housing facilities.

The Institutional Official was informed immediately of the suspension and the PI was provided prompt written notification. The OHSU Office of Programs and Award Management (OPAM) informed the funding agencies of the suspensions on June 27, 2019.

The IACUC notified the PI of corrections needed in order for the status of the two protocols to be reconsidered including:

1. Complete correction of all non-compliant items identified in the notice of suspension; and
2. Development and full implementation of a plan assuring proper control and oversight of the animal program by the PI in the PI's laboratory, such that appropriate standards for the care and use of animals as research subjects will be achieved and maintained on a continuing basis.

The PI recognized his responsibility for proper control and oversight of animal care and use in the laboratory, developed a correction plan and presented it to a convened meeting of the IACUC for consideration on July 17, 2019. The plan assured that:

1. DCM veterinarians will continue to have full access to all animals at all times.
2. All IACUC-approved protocols will be reviewed annually by laboratory personnel.
3. Standard operating procedures (SOPs) will be developed for observation of animal health and behavior, and post-procedural care. Veterinary consultation and approval of SOPs is required.
4. Oversight of animal care and use in the laboratory will be facilitated by the Research Assistant functioning as laboratory manager (hired June 17, 2019) who meets weekly with the PI and is responsible for monitoring daily animal care and use by management of the following activities and maintenance of related documentation:
 - a. weekly animal health checks with veterinary staff;
 - b. assuring compliance with approved SOPs for animal related activities;
 - c. training of staff in animal care and use;
 - d. maintaining surgical and procedural records;
 - e. assuring compliance with occupational health program requirements; and
 - f. maintaining an on-line calendar which is available to DCM veterinary staff and IACUC members that details planned animal activities and training sessions.
5. All laboratory members will sign a laboratory agreement indicating their understanding of the responsibilities for using animal models and stressing the importance of reporting animal health and welfare concerns.
6. Continuing education in animal welfare will be provided monthly by the senior faculty mentor for laboratory personnel and the PI. The IACUC, IACUC office staff and DCM veterinarians are also invited.
7. Signage will be posted prominently requiring staff to report potential animal health or compliance concerns.
8. Training including IACUC 101 and IACUC 201 will be completed by the PI.
9. Supplemental training through the AALAS Learning Library will be completed by the Research Assistant.

Additionally, the PI will provide a written report to the IACUC on a monthly basis for at least six months documenting the activities described above. The monthly report will include details of any unexpected outcomes and continued reporting may be required beyond the six-month period.

The plan of correction was approved by the IACUC and both protocols were reinstated via unanimous vote of the IACUC. The PI and laboratory staff were permitted access to the animal facilities on July 20, 2019.

All direct costs paid from NIH Grant 5RO1DC014950-04 and USAMRMC Award D15AP00101 that were associated with the care, housing and use of the animals during the non-compliant events were removed from these accounts and invoiced to and paid from a nonfederal source.

OHSU is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Vickie Jarrell, Ph.D., Director, Animal Care and Use Program, Office of Research Integrity.

Sincerely,

(b) (5)

Dana Director, Ph.D.
Vice President of Research Administration &
Senior Staff Officer
Institutional Official
Oregon Health & Science University

cc: IACUC Chair
Attending Veterinarian
Director, Animal Care and Use Program

A3304-30



Initial Report of Noncompliance

By: BGM

Date: 6/20/19

Time: Voicemail

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

After July 10 contact:
Vickie Janell @

or Chair

Name of Institution: Oregon Health & Sci. Univ.

Assurance number: A3304

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary): Yes

What happened? 2 protocols under one PI suspended.
Animals transferred to holding protocol,
Recurring issue.

Species involved: Ferrets, marmosets, gerbils, mice

Personnel involved: Researchers

Dates and times: April

Animal deaths: Yes, death of ferret due to surgical
issues, requiring euthanasia under anesthesia.
Euthanasia method not per protocol,

Projected plan and schedule for correction/prevention (if known):

PI on vacation, not yet notified.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #

Also, OHS (Occ. Health) issues re:
marmoset exposure,
Animal health record issues.

USDA also noted head caps not
properly maintained. (early June)



Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: 1046
Certificate: 92-R-0001
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 03-JUN-2019

2.32

PERSONNEL QUALIFICATIONS.

A lab group was found on April 2, 2019 to be conducting a surgery with poor sterile technique. Department of Comparative Medicine (DCM) veterinarians and technicians in attendance stepped in to ensure the welfare of the ferret. This pilot surgery ran into unexpected anatomical complications, and the animal was euthanized under anesthesia. The materials and methods for this euthanasia were not on the approved protocol.

The lab's training records were not current prior to the incident – copies provided were back-filled with training information and dates after the deficiencies in the lab were noted in April. The IACUC did not have personnel qualification information available at the time the protocol was approved.

The mitigation plan included a training covering scrubbing and gowning on 5/21/19. Two of the people in that training under the lab's protocol number are not listed as personnel on the approved protocol. It is unclear if they have participated in procedures.

The IACUC must evaluate qualifications of all personnel on the protocol, and ensure all personnel are listed on the protocol, as part of the approval process.

Correct by ensuring all aspects of Section 2.32 are met prior to approving protocols from this point forward.

2.33(b)(2) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In the same lab, there were containers of dressing supplies used for ferret cap care on the bench. The containers appeared dirty, and had large areas of corrosion on the lids and under the lid. The containers held gauze for cleaning and non-stick pads for dressing the caps.

Corroded metal cannot be adequately cleaned, disinfected, or sterilized. Their use is not appropriate for procedures requiring clean or sterile technique because they can harbor pathogens which may result in infection.

Correct by using containers able to be properly cleaned and disinfected or sterilized from this point forward.

Prepared By:

HALLBERG GWYNN, D V M

HALLBERG GWYNN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5036

Date:
11-JUN-2019

Received By:

Title:

Date:
11-JUN-2019



Inspection Report

2.33(b)(3) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

At the time of inspection, the same lab had a ferret (#100951) in a restraint for training and cap care. The ferret had a strong foul odor, and the cap margins were moist with crusty exudate. A second ferret (#270877B) in a holding cage was rubbing its head cap on the fabric of a hammock. Review of the protocol revealed that rubbing or itching of the surgery site will trigger notification to the DCM. Neither animal had been reported to the AV in the DCM. Both animals were immediately examined by DCM veterinarians and a treatment plan was initiated.

Correct by ensuring that, from this point forward, all animal use personnel are aware of the daily observation requirements in this section, and that they know that they must immediately report problems to the Attending Veterinarian.

This inspection and exit interview were conducted on June 3, 4, and 6, 2019 with facility personnel.

Prepared By:

HALLBERG GWYNN, D V M

HALLBERG GWYNN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5036

Received By:

Title:

Date:

11-JUN-2019

Date:

11-JUN-2019



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 03-JUN-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	03-JUN-19

Count	Scientific Name	Common Name
000004	<i>Callithrix jacchus</i>	COMMON MARMOSET
000031	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000028	<i>Meriones unguiculatus</i>	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000003	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000016	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000016	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000019	<i>Urocitellus parryii</i>	ARCTIC GROUND SQUIRREL / ARCTIC SOUSLIK
000117	Total	



Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: 1046
Certificate: 92-R-0001
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 19-JUL-2018

2.32(c)(3) CRITICAL

PERSONNEL QUALIFICATIONS.

A PI self-reported to the Department of Comparative Medicine (DCM) the deaths of two GPs post-procedure. The PI requested DCM veterinary review. The DVM veterinarian determined the anesthetic monitoring was inadequate. Training and instruction of personnel in the proper use of anesthetics must be provided to minimize risk of adverse events.

This was corrected prior to the time of inspection. The DCM evaluated the procedures and made recommendations for improvement which were successfully implemented.

3.28(a) CRITICAL

PRIMARY ENCLOSURES.

An adverse event was reported in the July 2017 IACUC minutes. A 4 month old guinea pig injured its leg in the perforated floor of newly-purchased bedding-free caging. It was thought to have gotten its foot caught in a corner hole, which was slightly larger than the other holes in the flooring. The animal failed to respond to treatment and was euthanized. Bedding-free flooring must allow waste to drop through, but protect feet and legs from injury. This was corrected quickly after the incident, prior to the time of inspection. The study was concluded shortly after this incident without further cases. The cage floors have since been replaced with solid-bottom flooring with bedding.

Another incident was reported in the October 2017 IACUC minutes. A guinea pig was injured when its leg got trapped in a damaged igloo. The animal was euthanized when it did not respond to treatment. Husbandry staff had not removed the damaged item as per policy. Items in the enclosure must be replaced when damaged to protect from injury. This was corrected prior to the time of inspection by retraining the staff on evaluating enrichment items for safety.

Prepared By:

HALLBERG GWYNN, D V M

HALLBERG GWYNN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5036

Received By:

Title:

Date:
26-JUL-2018

Date:
26-JUL-2018



Inspection Report

3.83

WATERING.

The female marmosets were found without water on a Saturday morning. It was determined that when they were returned to their home enclosure the previous afternoon, the IACUC-approved protocol for providing water was not followed, and they were without water overnight. They were given water; the animals displayed no ill effects. Animals must be given water as required by the IACUC-approved research protocol to ensure their health and comfort.

This was corrected immediately by giving the animals water as per protocol. The situation was reviewed by the IACUC prior to the time of inspection; laboratory staff was counseled regarding ensuring the protocol is strictly followed.

3.130

WATERING.

A surgery was postponed due to a miscommunication in a lab that resulted in a ferret going without water for approximately 24 hours. The Department of Comparative Medicine (DCM) veterinarian was notified; the ferret recovered fully with no ill effects.

Water must be provided as often as necessary to ensure the health and comfort of the animal. This animal is under an IACUC-approved protocol describing how and when water is to be provided, but the miscommunication resulted in deviation from the protocol's requirements.

This was corrected prior to the time of inspection. The lab personnel reviewed and revised their communication procedures to minimize the possibility of recurrence.

This inspection and exit interview were conducted on 7/17-19/2018 with facility personnel. A follow-up communication was conducted by telephone on 7/26/2018.

Prepared By:

HALLBERG GWYNN, D V M

HALLBERG GWYNN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5036

Date:

26-JUL-2018

Received By:

Title:

Date:

26-JUL-2018



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 19-JUL-18

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	19-JUL-18

Count	Scientific Name	Common Name
000004	<i>Callithrix jacchus</i>	COMMON MARMOSET
000049	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000075	<i>Meriones unguiculatus</i>	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000005	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000008	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000002	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000143	Total	

Jul 2018

- Perch incident
 - In May, an NHP was humanely euthanized due to an injury sustained in a containment area.
 - Perch design working group was convened to evaluate perch refinements.
 - USDA and OLAW have been notified of the incident and mitigation plan.
 - Approved the mitigation plan (11-For, 0-Against, 0-Abstained)
- Follow-up to pilot experiment with Cephoba
 - Protocol was modified to reduce the dose of Cephoba after an adverse reaction to a subcutaneous injection. There have been no adverse outcomes from the reduced dose.

Aug 2018

- Ferret Head Post complication
 - This lab studies normal auditory function. Ferret's head needs to be fixed in place for craniotomy & electrode placement. This requires head-post using acrylic & screws to attach to skull.
 - Three ferrets lost head caps in June. This didn't require immediate euthanasia, but did create an open wound. One ferret had head cap for 2 years. Granulation tissue is formed & eventually gets in between cap and skull, causing them to come off.
 - Two ferrets were euthanized for scientific reasons (end of study and unrelated to head cap issue). Third ferret is being treated with bandages to aid in healing.
 - Improvements to cleaning procedures, bandaging materials can improve outcomes. These changes have been implemented. Acrylic was changed out and screw placement assessed.
 - PI would like to re-implant the head cap on the third animal if approved by IACUC.
 - Lab staff is very communicative with DCM vets.